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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/671,317

09/25/2003

Hermann Oppermann

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06/27/2006

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EXAMINER

KEMMERER, ELIZABETH

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 06/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/671,317

Applicant(s)

OPPERMANN ET AL.

Examiner

Elizabeth C. Kemmerer, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 81,88 and 96 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 81,88 and 96 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11/17/03</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Status of Application, Amendments, And/Or Claims

The preliminary amendments of 25 September 2003 and 05 November 2004 have been entered in full.

Claims 1-80, 82-87, 89-95, and 97 are canceled. Claims 81, 88, and 96 are under examination.

35 U.S.C. § 112, First Paragraph, New Matter

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 81, 88, and 96 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 81, 88, and 96 recite an osteogenic protein defined by a cysteine skeleton. This structure is not disclosed in the specification as originally filed, and Applicant has not pointed to specific support of this claim language.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

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unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 81, 88, and 96 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the following:

- 1) claims 1-14, 16-23, 32-37 of U.S. Patent No. 5,011,691;
- 2) claims 1-17 of U.S. Patent No. 5,258,494;
- 3) claims 6-58 of U.S. Patent No. 5,266,683;
- 4) claims 1-3 of U.S. Patent No. 5,324,819;
- 5) claims 15-58 of U.S. Patent No. 5,354,557;
- 6) claims 1-12 of U.S. Patent No. 5,652,337;
- 7) claims 27-37 of U.S. Patent No. 5,656,593;
- 8) claims 14, 15, 19, 21, and 22 of U.S. Patent No. 5,674,292;
- 9) claims 1-12 of U.S. Patent No. 5,750,651;
- 10) claims 3-10, and 17-24 of U.S. Patent No. 5,814,604;

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- 11) claims 42 and 49 of U.S. Patent No. 5,863,758;
- 12) claims 1-34 of U.S. Patent No. 6,013,856;
- 13) claims 1-22 of U.S. Patent No. 6,022,853;
- 14) claim 8 of U.S. Patent No. 6,077,988;
- 15) claims 14, 17, 18, and 24-26 of U.S. Patent No. 6,110,482;
- 16) claim 10 of U.S. Patent No. 6,153,583;
- 17) claims 1-8 of U.S. Patent No. 6,211,146;
- 18) claims 11-15 and 18-20 of U.S. Patent No. 6,281,195;
- 19) claims 16, 17, and 20 of U.S. Patent No. 6,297,213;
- 20) claims 1-18 of U.S. Patent No. 6,461,630;
- 21) claims 1-15 of U.S. Patent No. 6,468,308;
- 22) claims 19, 20, 50, and 51 of U.S. Patent No. 6,504,079;
- 23) claims 13 and 14 of U.S. Patent No. 6,551,995;
- 24) claims 28-33 of U.S. Patent No. 6,586,388;
- 25) claims 1-13 of U.S. Patent No. 6,677,432; and
- 26) claims 1-10 of U.S. Patent No. 6,919,308

Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims recite particular osteogenic proteins which are species or subgenera of the genus of osteogenic proteins recited in the instant claims. A species or subgenus generally renders its genus unpatentable. The limitations regarding the device and method step of instant claims 88 and 96 are provided by the patented claims. Thus, issuance of the instant claims in the absence of

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terminal disclaimers may result in an unjustified or improper timewise extension of the "right to exclude" granted by a patent and potential harassment of the public by multiple assignees.

Specification

The disclosure is objected to because of the following informalities: The status of any patent application mentioned in the specification should be updated. Furthermore, Applicant is invited to review the specification for improper handwritten alterations.

Appropriate correction is required.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth C. Kemmerer, Ph.D. whose telephone number is (571) 272-0874. The examiner can normally be reached on Monday through Thursday, 7:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, Ph.D. can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ECK



ELIZABETH KEMMERER
PRIMARY EXAMINER